

§ 520.763

21 CFR Ch. I (4–1–05 Edition)

§ 520.763 Dithiazanine iodide oral dosage forms.

§ 520.763a Dithiazanine iodide tablets.

(a) *Chemical name.* 3-Ethyl-2-[5-(3-ethyl-2-benzothiazolinyldene)-1,3-pentadienyl]-benzothiazolium iodide.

(b) *Specifications.* Dithiazanine iodide tablets contain 10 milligrams, 50 milligrams, 100 milligrams, or 200 milligrams of dithiazanine iodide in each tablet.

(c) *Sponsor.* See No. 000010 in § 510.600(c) of this chapter.

(d) *Conditions of use.* (1) The tablets are administered orally to dogs immediately after feeding using the following dosage schedule for various parasite infestations:

	Milligrams per pound of body weight	Length of treatment—days
Large roundworms (<i>Toxocara canis</i> , <i>Toxascaris leonina</i>)	10	3–5
Hookworms (<i>Ancylostoma caninum</i> , <i>Uncinaria stenocephala</i>)	10	7
Whipworms (<i>Trichuris vulpis</i>)	10	
Strongyloides (<i>Strongyloides canis</i> , <i>Strongyloides stercoralis</i>)	10	10–12
Heartworm microfilariae (<i>Dirofilaria immitis</i>)	3–5	7–10

Note: Treatment with dithiazanine iodide for heartworm microfilariae should follow 6 weeks after therapy for adult worms.

(2) The drug is contraindicated in animals sensitive to dithiazanine iodide and should be used cautiously, if at all, in dogs with reduced renal function.

(3) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(e) Use for treating dogs for large roundworms, hookworms, whipworms, and strongyloides as provided for in this section has been NAS/NRC reviewed and deemed effective. Applications for these uses need not include effectiveness data as specified by § 514.111 of this chapter, but may require bioequivalency and safety information.

[40 FR 13838, Mar. 27, 1975, as amended at 47 FR 51564, Nov. 16, 1982; 48 FR 32342, July 15, 1983; 53 FR 40727, Oct. 18, 1988; 62 FR 35076, June 30, 1997]

§ 520.763b Dithiazanine iodide powder.

(a) *Chemical name.* 3-Ethyl-2-[5-(3-ethyl-2-benzothiazolinyldene)-1,3-pentadienyl]-benzothiazolium iodide.

(b) *Specifications.* Dithiazanine iodide powder contains 200 milligrams of dithiazanine iodide per level standard tablespoon.

(c) *Sponsor.* See No. 000010 in § 510.600(c) of this chapter.

(d) *Conditions of use.* (1) Dithiazanine iodide powder is administered to dogs by mixing the proper dosage in the dog's food, using the following dosage schedule for various parasite infestations:

	Milligrams per pound of body weight	Length of treatment—days
Large roundworms (<i>Toxocara canis</i> , <i>Toxascaris leonina</i>)	10	3–5
Hookworms (<i>Ancylostoma caninum</i> , <i>Uncinaria stenocephala</i>)	10	7
Whipworms (<i>Trichuris vulpis</i>)	10	7
Strongyloides (<i>Strongyloides canis</i> , <i>Strongyloides stercoralis</i>)	10	10–12
Heartworm microfilariae (<i>Dirofilaria immitis</i>)	3–5	7–10

Note: Treatment with dithiazanine iodide for heartworm microfilariae should follow 6 weeks after therapy for adult worms.

(2) The drug is contraindicated in animals sensitive to dithiazanine iodide and should be used cautiously, if at all, in dogs with reduced renal function.

(3) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(e) Use for treating dogs for large roundworms, hookworms, whipworms, and strongyloides as provided for in this section has been NAS/NRC reviewed and deemed effective. Applications for these uses need not include effectiveness data as specified by § 514.111 of this chapter, but may require bioequivalency and safety information.

[40 FR 13838, Mar. 27, 1975, as amended at 47 FR 51564, Nov. 16, 1982; 48 FR 32342, July 15, 1983; 53 FR 40727, Oct. 18, 1988; 62 FR 35076, June 30, 1997]

§ 520.763c Dithiazanine iodide and piperazine citrate suspension.

(a) *Specifications.* Each milliliter of the drug contains 69 milligrams of dithiazanine iodide and 83 milligrams